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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,241

09/05/2007

Peixuan Guo

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MUETING, RAASCH & GEBHARDT, P.A.

P.O. BOX 581336

MINNEAPOLIS, MN 55458-1336

EXAMINER

CHONG, KIMBERLY

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/539,241	<b>Applicant(s)</b> GUO ET AL.	
	<b>Examiner</b> KIMBERLY CHONG	<b>Art Unit</b> 1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

**REQUIREMENT FOR UNITY OF INVENTION**

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3)A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4)A process and an apparatus or means specifically designed for carrying out the said process; or

(5)A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1: Claims 1-8, 28 and 35-37, drawn to a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers, wherein the monomer comprises a biologically active ribozyme, classifiable in class 536, subclass 24.5. This group is subject to a further species election as per below.

Group 2: Claims 1-8, 28 and 35-37, drawn to a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers, wherein the monomer comprises a

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biologically active siRNA, classifiable in class 536, subclass 24.5. This group is subject to a further species election as per below.

Group 3: Claims 1-8, 28, 30 and 35-37, drawn to a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers, wherein the monomer comprises a biologically active RNA aptamer, classifiable in class 536, subclass 24.5. This group is subject to a further species election as per below.

Group 4: Claims 1-8, 28, 29 and 35-37, drawn to a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers, wherein the monomer comprises a biologically active antisense RNA, classifiable in class 536, subclass 24.5. This group is subject to a further species election as per below.

Group 5: Claims 1-8, 28 and 35-37, drawn to a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers, wherein the monomer comprises a biologically active PNA, classifiable in class 536, subclass 24.5. This group is subject to a further species election as per below.

Group 6: Claims 1-8, 28 and 31-37, drawn to a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers, wherein the monomer comprises an end labeling agent, classifiable in class 536, subclass 24.5. This group is subject to a further species election as per below.

Group 7: Claims 17 and 18, drawn to a method for delivering a therapeutic agent to a cell comprising contacting the cell with a polyvalent multimeric complex, classifiable in class 514, subclass 44.

Group 8: Claims 38-48, drawn to a method for making a polyvalent multimeric complex comprising RNA monomers wherein the monomers comprise a biologically active component, wherein the component is a targeting agent, classifiable in class 435, subclass 6. This group is subject to a further species election as per below.

Group 9: Claims 38-48, drawn to a method for making a polyvalent multimeric complex comprising RNA monomers wherein the monomers comprise a biologically active component, wherein the component is a therapeutic agent, classifiable in class 435, subclass 6. This group is subject to a further species election as per below.

Group 10: Claims 38-48, drawn to a method for making a polyvalent multimeric complex comprising RNA monomers wherein the monomers comprise a biologically active component, wherein the component is a labeling agent, classifiable in class 435, subclass 6. This group is subject to a further species election as per below.

The inventions listed as Groups 1-6 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

Groups 1-6 lack unity of invention because the groups do not share the same or corresponding technical feature. The special technical feature of group 1 is a ribozyme which is not shared with groups 2-6. The special technical feature of group 2 is a siRNA, which is not shared with groups 1 or 3-6. The special technical feature of group

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3 is an aptamer, which is not shared with groups 1-2 or 4-6. The special technical feature of group 4 is an antisense, which is not shared with groups 1-3 and 5-6. The special technical feature of group 5 is a PNA, which is not shared with groups 1-4 and 6. The special technical feature of group 6 is a PNA, which is not shared with groups 1-5. Therefore, because groups 1-6 lack the same or corresponding special technical feature, unity of invention is lacking and restriction is proper.

Groups 1-6 and Group 7 lack unity of invention because the groups do not share the same or corresponding technical feature. The special technical feature of groups 1-6 is a polyvalent complex and the special technical feature is a method for delivering a therapeutic agent to a cell. Therefore, because groups 1-6 and group 7 lack the same or corresponding special technical feature, unity of invention is lacking and restriction is proper.

Groups 1-6 and Groups 8-10 lack unity of invention because the groups do not share the same or corresponding technical feature. The special technical feature of groups 1-6 is a polyvalent complex and the special technical feature of groups 8-10 is a method for making a polyvalent multimeric complex. Therefore, because groups 1-6 and groups 8-10 lack the same or corresponding special technical feature, unity of invention is lacking and restriction is proper.

Groups 7 and Groups 8-10 lack unity of invention because the groups do not share the same or corresponding technical feature. The special technical feature of group 7 is a method of delivering a therapeutic agent and the special technical feature of groups 8-10 is a method of making a polyvalent multimeric complex. Therefore, because groups 7 and groups 8-10 lack the same or corresponding special technical feature, unity of invention is lacking and restriction is proper.

Groups 8-10 lack unity of invention because the groups do not share the same or corresponding technical feature. The special technical feature of group 8 is a targeting agent which is not shared with groups 9-10. The special technical feature of group 9 is a therapeutic agent, which is not shared with groups 8 or 10. The special technical feature of group 10 is an end-labeling agent, which is not shared with groups 8-9. Therefore, because groups 8-10 lack the same or corresponding special technical feature, unity of invention is lacking and restriction is proper.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: Claims 4 and 32 patentably distinct end labeling agents. Claims 8, 34, 37 and 46 are directed to patentably distinct nucleotide analogs.



Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: 1, 28, 35 and 45.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/  
Primary Examiner  
Art Unit 1635